Goals: The purpose of this rotation is to familiarize the student with the role of the Food and Drug Administration (FDA) in the drug development, review, and post-marketing phases, with special emphasis on FDA's role regarding abuse liability assessment of neuro-active drug substances, drug scheduling, abuse, and dependence, including international drug scheduling and control.

Describe the Learning Objectives:

I. Upon completion of this rotation the student will be able to:

A. Describe the development of a new drug from laboratory to commercial distribution of the product and the FDA's role in that process.

B. Distinguish between the three phases of clinical trials in the drug development process, and understand the necessary data needs for assessing abuse liability of drug substances at each of these phases.

C. Discuss ways the FDA assesses abuse liability of drug substances prior to approval as per published FDA Guidance on this subject.

D. Understand the different roles of FDA and the U.S. Drug Enforcement Administration in the drug scheduling process and maintaining drug availability while controlling abuse and diversion.

E. Outline the post marketing surveillance mechanisms the FDA uses to monitor the general drug safety as well as the misuse and abuse of marketed drugs containing controlled substances.

F. Utilize drug information, FDA resources, and online Pub Med literature searches as necessary to research assigned project topic. The student will work closely with both their preceptor and other professional staff, who will provide guidance and assistance to the student for successful completion of this project.

G. Answer questions become familiar with the Federal laws and regulations governing changes in control of both illicit and marketed controlled substances, and the major provisions of international treaties for controlling the manufacturer and distribution of licit controlled substances worldwide. These include the FD&C Act, the U.S. Controlled Substances Act, and the 1961 and 1972 International drug control treaties.

II. Student Requirements: The student will be exposed to a variety of issues regarding many aspects of the drug development process such as abuse liability assessment, drug dependence and overdose drug labeling requirements, and international Depending on issues are currently being. The program will focus on familiarizing the

student with the type of information collected and what is releasable from the FDA. To meet these objectives the student will be expected to:

A. Complete and present to CSS staff a PowerPoint presentation on a CSS-assigned project topic. This project topic will be assigned by the director and is directly related to the information needs at the time of the rotation. In some cases a short project write-up report is required.

B. Attend core student rotation lectures within the Office of the Commissioner and the Center for Drug Evaluation and Research.

C. Fulfill required hours.